## Media:V1.6 release notes- 11.26.08.doc

Release Notes

caAERS Version 1.6 November 26, 2008

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# 1.0 caAERS Introduction and History

## History:

The caAERS application development project began on December 1, 2006. The goal of this project is to develop and to deploy an adverse event reporting system that is nationally scalable with a robust architecture to meet the needs of the caBIG? Community.

caAERS is a product of the NCI Center for Bioinformatics and its partners. Visit the caAERS Knowledge Center web site for more information:

## CaAERS Knowledge Center

# Description of caAERS:

The Cancer Adverse Event Reporting System (caAERS) is an open source, web- based application for documenting, managing, reporting, and analyzing adverse events (AEs). The system operates as both a repository for capturing and tracking routine and serious AEs and as a tool for preparing and submitting expedited AE reports to regulatory agencies. Currently, caAERS works with cancer prevention and

therapeutic trials and can accommodate a range of intervention types, including investigational and commercial agents, radiation, surgery, and medical devices. Adverse events can be coded in caAERS using either CTC or MedDRA.

To help organizations stay in compliance with AE reporting regulations, the caAERS application comes loaded with a full complement of industry-standard AE reports, including the FDA MedWatch 3500A form, the CTEP AdEERS reports, and the NCI-DCP SAE form. In addition, the caAERS system features a powerful, state-of- the-art rules engine, which can capture a range of sponsor, institution, and protocol- level reporting requirements. Using these rules, caAERS can automatically determine if an adverse event requires expedited reporting and when and to whom the report must be submitted -- for any of an organization's trials. The business rules used by caAERS can be authored within the application itself or imported from a library of approved rule sets.

caAERS also features an advanced email-based alert system that can be customized along a number of dimensions (message content, recipients, delivery times) to ensure that notifications and reminders are sent out as needed.

caAERS can be deployed as a stand-alone application or as an integrated module within the caBIG? Clinical Trials Suite CCTS).

# 2.0 caAERS Release History

Below is listed the recent release history of caAERS.

#### caAERS v1.5

-- 25 September 2008

#### caAERS v1.5.1

-- 10 October 2008

# 3.0 New Features and Updates

The following new features and enhancements have been implemented in since the previous production release:

- Verbatim added for solicited AEs
  - ◆ Required for DCP and FDA reporting
- Other, Specify added for solicited AEs
  - ♦ Important to allow configuration of solicited AEs for non-CTCAE terms

- Report definition export/import feature
  - ♦ Significantly reduces configuration time after a new install or an upgrade.

Allows sharing of report definitions, including a way to support standard reports.

- Locking/notification for AE?s included in a submitted report
- ♦ Ensures that changes to AEs included in submitted reports result in a report amendment.
  - On backend, implemented a save feature for submitted pdf and xml
- ♦ Important for auditing purposes. These files can be accessed through direct database queries.
  - Expanded study diseases to include user addable conditions
- ♦ Critical for the support of prevention studies as study participants many not have a disease.
  - Ability to save AE data entry which is partially complete
- ♦ This is critical for fitting into the current business practices where an AE term may be added, but not graded or attributed due to additional investigation.
  - Changed the ?Report? button to ?Continue?\*\*This is an important update in that it properly treats reporting as a flow, but

also the functionality has changed to allow user to access in-process and submitted reports via this flow.

- Improved the readability of report status messages on the Manage Reports tab
- Added business rule validations to study and participant data entered into the system via XML import or message and Excel import.
- ♦ This is a critical improvement to ensure the integrity of data entered into the system via imports and messaging meets the same requirements as data entered via the user interface.
  - Added read only(view) feature for Studies and Participants.
  - Updated the expand/collapse icon from a triangle to a more intuitive icon (a plus or minus in a box).

# 4.0 Bugs Fixed Since Last Release

- Fixed issue w/ MedWatch pdf generation and rendering on certain computers.
- Updated the business rules regarding subjects to enforce a unique assigned identifier for subjects at a given site.
  - Fixed mapping of investigational agent administered field in AdEERS report.
  - Fixed the generation of improper WSDL?s for the Investigator and ResearchStaff

Services.

♦ This was due to the interface having a few unwanted method signatures. Both

interfaces have been fixed and they now have exposed one method each. Additionally, there were two (2) schemas involved in Investigator and two (2) schemas involved in ResearchStaff Services. The generated WSDL's did not contain these schemas. This has been resolved and now both the WSDL?s contain the necessary schemas.

- Fixed issue where they system did not recognize the 31st of any month as a valid date.
- Fixed issue where a device name was not appearing on the attribution tab in the adverse event reporting flow.
  - Fixed several rights and permissions issues associated with certain roles.
- Fixed the issue where a study participant could be assigned to a study site different than the site associated with the participant.
  - Fixed issue with CTCv2.0 grades not being properly populated within the system.
  - Fixed issue where investigators were not able to be associated with a Coordinating Center or Lead Organization via the XML imports or messaging.

## 5.0 Known Issues

• caAERS is not yet approved for use by CTEP for expedited reporting to AdEERS.

Piloting activities are in process that will address this within the next several releases.

• The AdEERS web service currently requires Agents to be included for Prior

Therapies of types: ?Bone Marrow Transplant?, ?Chemotherapy NOS?, ?Chemotherapy Multiple Agents Systemic?, ?Chemotherapy Single Agent Systemic?, ?Hormonal Therapy?, and ?Immunotherapy.? This requirement currently is not enforced in the AdEERS user interface and will be removed as a requirement for the web service on or before 12/12/2008. In preparation for this change to the AdEERS web service, this rule has been eliminated within the caAERS user interface. Please note that prior to the update to the AdEERS web service, users will be required to include an Agent for the above Prior Therapies in order to submit an expedited report to AdEERS via caAERS.

- Some pages are incompatible with the Internet Explorer v.6 browser. Plans to support this browser are being evaluated. Use of Internet Explorer v7 and Firefox v2.0 and up are supported.
- There are some data items available in the user interface which are not yet available for entry via services or imports. Efforts to update the services and imports are currently underway.
- they are not associated is not working properly. This is currently being fixed and will be included in an upcoming release.

• The site filtering which prevents users from accessing content from sites to which

• Dose Modified and Administration Delay fields are tied together in AE reporting flow in a way

that is inconsistent with previously submitted reports. The current work around is to enter "0" for Administration Delay if there is no delay and enter the Dose administered for Dose Modified. This issue is currently being evaluated.

# 6.0 Documentation and Support

The CTMS Knowledge Center is the primary source of documentation and support for production releases of caAERS:

# CaAERS Knowledge Center

Through this site, you can obtain all installation, administration, and user documentation. Additionally, this is the appropriate forum to report bugs and issues. You can also access the caAERS development team through this site.